510(K) SUMMARY

This summary of 510(K) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(K) number is: K132201

1. **Submitter's Identification:**
   Zibo Intco Medical Products, Co. Ltd.
   No. 18, Qingtian Road, Linzi District
   Qilu Chemical Industry Park
   Zibo City, Shandong Province
   China

   Contact Person
   John Zhao
   Tel: 909-548-4828, Fax: 909-548-4808

NOV 27 2013

Date summary prepared: Nov. 4, 2013

2. **Name of the Device:**
   Synmax Synthetic Examination Vinyl Gloves,
   Powder Free, Blue

3. **Common Name:**
   Synmax Synthetic Examination Vinyl Gloves,
   Powder Free, Blue

4. **Predicate Device Information:**
   Shijiazhuang Eversharp Plastic Products Co., Ltd.
   Synthetic Powder Free (Yellow) Vinyl Examination Gloves (K011882)

5. **Device Description:**
   Classified by FDA's General and Plastic Surgery Device panel as Class I, 21 CFR 880.6250, Examination Vinyl Glove, 80LYZ, and meets all requirements of ASTM Standard D5250-06.

6. **Intended Use:**
   A patient examination glove is a disposable device intended for medical purposes that is worn upon the examiner's hands or fingers to prevent contamination between patient and examiner.(21 CFR 880.6250)

7. **Comparison to Predicate Devices:**
   Zibo Intco Medical Products, Co. Ltd.'s Synmax Synthetic Examination Vinyl Gloves, Powder Free, Blue is substantially equivalent in safety and effectiveness

to Shijiazhuang Eversharp Plastic Products Co., Ltd. Synthetic Powder Free (Yellow) Vinyl Examination Gloves (K011882). Please see table 7-2 for comparison details.

8. **Discussion of Non-Clinical Test Performed for Determination of Substantial Equivalence are as Follows:**
The standards used for Zibo Intco Medical Products, Co. Ltd. glove production are based on ASTM-D-5250-06. All testing meets requirements for Physical and Dimensions Testing conducted on gloves, Inspection Level S-2, AOL 2.5.

The FDA 1000 ml. Water Fill Test was also conducted with samplings of AOL 2.5, Inspection Level I, meeting these requirements, Primary Skin irritation and Skin Sensitization (allergic contact dermatitis) testing was conducted with results showing no primary skin irritant or sensitization reactions.

There are no special labeling claims and we do not claim our gloves as hypoallergenic is conducted to insure that our gloves meet our "powder-free" claims (contain no more than 2 mg powder per glove).

9. **Sterilization**
There is no specific device for non-sterile examination gloves. Hand hygiene by rubbing with an alcohol-based hand rub or by washing with soap and water should be performed when appropriate.

10. **Discussion of Clinical Tests Performed:**
Not Applicable – There is no hypoallergenic Claim.

11. **Conclusions:**
Zibo Intco Medical Products, Co. Ltd. Synmax Synthetic Examination Vinyl Gloves, Powder Free, Blue, conform fully to ASTM-D-5250-06 standard as well as applicable 21 CFR references, and, meets pinhole FDA requirements, biocompatibility requirements and labeling claims as shown by data in Section 7. There are no safety/efficacy issues or new claims from the "substantial equivalence" products cited.

Table 7-2. Side-by-Side Comparison of Intended Use, Design, Material, Physical, Biocompatibility, and Performance Testing

	Proposed Device	Predicate Device (K051662)
Description	Zibo Inteo Medical Products, Co. Ltd. Synmax Synthetic Examination Vinyl Gloves, Powder Free, Blue	Shijiazhuang Eversharp Plastic Products Co., Ltd. Synthetic Powder Free (Yellow) Vinyl Examination Gloves (K011882)
Indication for Use	A patient examination glove is a disposable device intended for medical purposes that is worn upon the examiner's hands or finger to prevent contamination between patient and examiner.	Substantially equivalent
Labeling: Instruction for use	A garment covering the hand and wrist area. That is a disposable device which is worn upon the examiner's hands or fingers to prevent contamination between patient and examiner.	Substantially equivalent
Labeling: Labels on the carton	Labels include: Product name; color; "single use only" size, piece count, lot number, distributor name, and manufacturer address.	Substantially equivalent
Device Materials	Poly Vinyl Chloride Polyurethane Diisononyl Phthalate (DINP)	Substantially equivalent
Before Aging: Tensile Strength(Mpa) and Ultimate Elongations	Average Tensile Strength (Mpa): 16.9 Average Ultimate Elongations: 550%	Substantially equivalent
After Aging: Tensile Strength(Mpa) and Ultimate Elongations	Average Tensile Strength (Mpa): 14.4 Average Ultimate Elongations: 500%	Substantially equivalent
Overall Length on Medium Size	Average over 230mm	Substantially equivalent
Width of Palm on Medium Size	Average 95mm	Substantially equivalent
Palm Thickness	Average 0.095 mm	Substantially equivalent
Figure Thickness	Average 0.090 mm	Substantially equivalent

Residual Powder	According to ASTM D6124-06 Standard Test Method for Residual Powder on Medical gloves for the determination of residual powder content. Testing result indicates the weight of all types of residual or powder on finished powder-free gloves as < 2 mg per glove and there is no defect glove found according to ASTM D6124-06.	Substantially equivalent
Pinhole Results	According to ASTM D5151-06, Testing result indicates pinhole were found less than two pieces gloves out of 125 pieces gloves. AQL 2.5 is met.	Substantially equivalent
Biocompatibility Result: Primary Skin Irritation	ISO 10993-10 passes	Substantially equivalent
Dermal Sensitization	ISO 10993-10 passes	Substantially equivalent
Summary of comparison	Zibo Intco Medical Products, Co. Ltd. Synmax Synthetic Examination Vinyl Gloves, Powder Free, Blue (subject device) and Shijiazhuang Eversharp Plastic Products Co., Ltd.Synthetic Powder Free (Yellow) Vinyl Examination Gloves (K011882) (predicate device) are substantially equivalent in all technological characteristics, including tensile strength, ultimate elongations size, thickness, residual powder and pinhole.	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 27, 2013

Zibo Intco Medical Products Company, Limited
C/O Mr. John Zhao
Official Correspondent
Basic Medical Industries, Inc.
12390 East End Avenue
CHINO CA 91710

Re: K132201
Trade/Device Name: Synmax Synthetic Examination Vinyl Gloves, Powder Free, Blue
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LYZ
Dated: October 28, 2013
Received: October 31, 2013

Dear Mr. Zhao:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin Keith

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132201

Device Name
Synmax Synthetic Examination Vinyl Gloves, Powder Free, Blue

Indications for Use *(Describe)*
A patient examination glove is a disposable device intended for medical purposes that is worn upon the examiner's hands or fingers to prevent contamination between patient and examiner.(21 CFR 880.6250)

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Elizabeth F. Claverie -S
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